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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,048	03/15/2001	Mario Carlone	53130/29870	7289

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Kent A. Herink  
Davis, Brown, Koehn, Shors & Roberts, P.C.  
2500 Financial Center  
666 Walnut Street  
Des Moines, IA 50309

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/811,048

Applicant(s)

CARLONE, MARIO

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 4, 12, 15, and 16 is withdrawn, in light of the claim amendments.

### ***Information Disclosure Statement***

3. The listing for "M.P. Rolston" in the 1449 form submitted with the papers on 24 February 2003 was lined through, because a copy of the reference has not been received.

### ***Claim Objections***

4. Claim 18 is objected to because of the following informalities: in line 4, "indentifying" is misspelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1-18 remain and claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 17 September 2002 under item 3. Applicant traverses the rejection in the paper received 24 February 2003. Applicant's arguments were fully considered, but were not found persuasive for the aspects of the rejection discussed below.

Regarding the recitation "G3601" in claims 1, 3, 5, 6, 9, 14, and 17: Applicant requests that the rejection be withheld until there are allowable claims, and that the deposit accession number will be provided later in the prosecution if the issue fee is to be paid (response, page 1, last paragraph). Applicant's intent to amend the claims to recite the deposit accession number at the time of allowance is acknowledged. However, the deposit statement on page 29 of the specification does not state that the viability of the biological material will be tested at the time of deposit, as required by 37 CFR 1.807. All of the conditions of deposit as required in 37 CFR 1.801-1.809 must be met. Also see MPEP 2411.02.

Regarding the recitation "protoplasts" in claim 4: Applicants argue that the claim has been amended to clarify that the protoplasts are formed from the cells in the tissue culture (response, page 2, 1<sup>st</sup> paragraph). However, the amended claim is confusing. It is not clear if the claim is drawn to the tissue culture of regenerable cells, or to cells or protoplasts produced from the tissue culture. It is suggested that the recitation "produced from the tissue culture, said tissue culture" be replaced with --of said cells--.

Regarding claim 18: the original claim was rejected because the meaning of the recitation "using the seed and its progeny" was not clear, and because the last step of the method claim was not consistent with its preamble. However, the claim amendments do not overcome the issues. The first line indicates that the claim is directed to a method for identifying the inbred seed G3601. However, the steps indicate that less robust hybrid plants (one of the parents of the hybrid seeds is presumably G3601) are selected, selfed, and the resultant seed are identified as the same as G3601. However, these selfed hybrids cannot produce inbred G3601 seed. The last step cannot result in G3601 seed. The claim remains confusing.

In claim 19: the recitation "wherein identifying the seed as an inbred seed" renders the claim indefinite. Claim 19 indicates that the method is for identifying G3601 seed. However, the recitation implies that the inbred seed can be any inbred, thereby broadening the scope of the claim from which it depends. Words also appear to be missing from the last line of the claim.

In claim 9: the claim is indefinite because words appear to be missing between "number X" in line 2 and "the process of" in line 3.

In claims 12 and 13: the claims are indefinite because it broadens the scope of claims 1 and 2. The seed and plant of claims 1 and 2 do not comprise transgenes.

In claims 15 and 16: the claims are indefinite because it broadens the scope of claims 1 and 2. Claims 1 and 2 do not make any mention of mutant genes.

6. Claims 6-18 remain and claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 17 September 2002 under item 4. Applicant traverses the rejection in the paper received 24 February 2003. Applicant's arguments were fully considered, but were not found persuasive.

Applicant first appears to be addressing an argument that the PTO supposedly made citing *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) (response, paragraph bridging pages 2-3). However, the first Office action does not make reference to this case. Applicant argues that Table 4 in the specification shows that G3601 in 30

different hybrid combinations. Applicants argue that Applicants have at least 15,000 seeds having as an G3601 (response, page 2, 2<sup>nd</sup> full paragraph). However, the specification does not provide the morphological and physiological traits of these hybrids. The specification does not provide criteria by which one may identify a corn plant as having G3601 as an ancestor.

Applicant also argues the Examiner "does not indicate any appreciation for the skill level of the ordinarily skilled person in the art", and that by definition, a plant breeder clearly is aware of the pedigree of a plant (response, paragraph bridging pages 2-3). However, the description of claimed inventions are not for those in the art to determine. Descriptions of claimed inventions must be supplied by the specification. Applicant argues that the ancestry of a plant can be traced with modern genetic techniques (response, paragraph bridging pages 2-3). However, the specification does not describe the molecular information of G3601 or the claimed hybrids that one skilled in the art would need for those techniques.

Applicants argue that methods for tracking pedigrees, detecting genetic carry over, and detect genetic movement of traits has been in use by the ordinarily skilled person in the art at least (since) the late eighties (response, page 3, 1<sup>st</sup> full paragraph). However, the specification does not provide a description of markers associated with any of the traits that are expressed by G3601, which those in the art require to detect genetic movement. The specification does not describe any marker that is unique to G3601. Applicants argue that maize traits are heritable. However, the specification does not describe how one would identify traits as having been inherited from G3601 versus other corn plants. The individual traits expressed by G3601 are not unique to that plant line. Applicants argue that a book written by M. Lynch and B. Walsh lists a number of molecular markers and the genetic material that these markers are detecting (response,

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paragraph bridging pages 3-4). However, the specification does not teach that markers possessed by G3601, nor the traits that they are associated with. It is also noted that Applicant's have not supplied a copy of the references mentioned on page 3 of their response.

Applicants again argue that the Examiner is ignoring the level of skill of plant breeders, that breeders move traits, mutations, and transgenes into new germplasms (response, page 4, 1<sup>st</sup> full paragraph). Again, the Examiner emphasizes that the level of skill of plant breeders is not the issue. Applicants have not described any of the claimed mutations. The specification does not describe the genes of G3601 that are mutated. Concerning claims reciting transgenes: the specification does not describe the morphological and physiological traits of G3601 as it is affected by any particular type of transgene. It is suggested that the claims be amended to recite that type of transgenes contemplated, provided that the specification or prior art described those isolated genes (for example, transgenes conferring plant virus resistance).

7. Claims 1-18 remain and claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 17 September 2002 under item 5. Applicant traverses the rejection in the paper received 24 February 2003. Applicant's arguments were fully considered, but were not found persuasive.

Applicant requests that the rejection be withheld until there are allowable claims, and that the deposit accession number will be provided later in the prosecution if the issue fee is to be

paid (response, page 1, last paragraph). Applicant's intent to amend the claims to recite the deposit accession number at the time of allowance is acknowledged. However, the deposit statement on page 29 of the specification does not state that the viability of the biological material will be tested at the time of deposit, as required by 37 CFR 1.807. The rejection will be withdrawn upon receipt of written assurance that the deposit will meet all of the conditions outlined in 37 CFR 1.801-1.809. Also see MPEP 2411.02.

***Claim Rejections - 35 USC § 102/103***

8. Claims 6-11 and 14 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson (U.S. Patent No. 5,880,342), for the reasons of record stated in the Office action mailed 17 September 2002 under item 5. Applicant traverses the rejection in the paper received 24 February 2003. Applicant's arguments were fully considered, but were not found persuasive.

Applicant argues that Table 9 shows that 17DIA1 and G3601 differ (response, paragraph bridging pages 5-6). Table 9 of Johnson presents and isozyme profile of 17 DA1, and three other corn lines. G3601 is not mentioned in Table 9. No conclusions can be made concerning differences between 17 DIA1 and G3601 from Table 9. Applicants argue that the table of column 7 (it is assumed Applicant is actually referring to Table 4) indicates differences in a few traits between 17DIA1 and those for G3601 (response, page 6, 1<sup>st</sup> full paragraph). This argument was found persuasive to withdraw the rejection from claims 1-5, 12, 13, and 18.

Applicant argues that the instant claims require the use of G3601, and that there is no likelihood that someone breeding with 17 DIA1 would achieve the invention (response, page 6,



last paragraph). However, prior art plants and seeds (hybrid corn plants and seeds of Johnson) having the same characteristics as the instantly claimed plants and seeds would anticipate the claimed products even if made by a different method (i.e., different parent plants). Here, the instant claims do not place any limitation on the morphological and physiological properties of the claimed plants and seeds themselves, and it is unknown if they differ from that of the plants and seeds taught by the reference. The hybrid plants and seeds taught by Johnson anticipate the instantly claimed hybrid plants and seeds, as their properties do not distinguish each other. As the claims do not place any phenotypic restrictions on the claimed products, the Examiner does not have sufficient facts to determine whether the progeny plants and seeds are inherently the same on this basis. The Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ from teachings of the reference, keeping in mind that it is the claimed products, not the process by which they are made, that must differ. Information concerning the genome of G3601, which would identify and distinguish it from the genome of other corn lines, and which would identify a corn plant or seed as an F1 progeny of G3601, is not available. The instant specification describes G3601 only on the basis of traits that it expresses. Where the prior art product seems to be identical, except that the prior art is silent as to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

9. Claims 1-18 remain and claims 19-20 are rejected.

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***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

May 9, 2003

  
**ASHWIN D. MEHTA, PH.D**  
**PATENT EXAMINER**